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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE RIGEL PHARMACEUTICALS, INC. SECURITIES LITIGATION

This Document Relates To: All Actions

Master File No. CV 09-0546 JSW

CLASS ACTION

RIGEL AND INDIVIDUAL DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS CONSOLIDATED COMPLAINT

Date:	December 4, 2009
Time:	9:00 a.m.
Courtroom:	11, 19th floor
Judge:	Hon. Jeffrey S. White

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

In reviewing Plaintiff's opposition brief, a number of critical issues become clear. First, it is clear that this is a case not about allegedly affirmative misrepresentations but rather about the alleged omission of material facts. As Plaintiff states, "The statements [regarding the results of the Phase IIa clinical study] were materially false and misleading because defendants failed to disclose critical adverse information." (Opp. at 5:7-8.) Plaintiff does not allege or argue that the trial failed to demonstrate the efficacy of R788 in the treatment of RA as Rigel disclosed in December 2007. Nor does it allege that the Company made false statements in 2007 regarding the adverse events (or side effects) observed during the trial. Rather, Plaintiff complains that the Company should have disclosed more detail about those adverse events; that is, that it concealed the risks that were identified during the trial.

Second, it is clear that the additional details Plaintiff claims should have been disclosed relate to adverse events that were milder and less significant than the adverse events disclosed by the Company. For example, Plaintiff does not dispute that the Company accurately disclosed that fifteen patients in the trial experienced neutropenia severe enough to require a reduction in their dosage of R788; rather, it argues that the Company should have also disclosed that five other patients experienced milder levels of neutropenia that did not require any dose reductions. Similarly, Plaintiff does not dispute that the Company accurately reported that only two patients experienced hypertension of a moderate or greater degree; rather, it argues that the Company should have disclosed that three other patients experienced lower levels of hypertension and that there was a small average increase in blood pressure observed in the patients. Plaintiff's complaint is, in essence, that every bit of patient data should have been disclosed, a complaint that can be made regarding every clinical trial absent the disclosure of the trial's raw data.

And third, it is clear that Plaintiff has failed completely to assert allegations that support an inference that Defendants acted with the requisite scienter that is at least as compelling as the inference that Defendants acted in good faith, based on the allegations and material subject to judicial notice. Plaintiff fails to identify a single contemporaneous report, a single email or a single witness in the Complaint that would support an inference of scienter. Rather, Plaintiff

relies on tired and routinely rejected assertions that Defendants were motivated by a desire to raise capital and to line their own pockets through higher salaries and bonuses. The problem with that theory is that it cannot be reconciled with the undisputed fact that the Company disclosed all the allegedly concealed data during the ACR conference and in an article in a medical journal in the fall of 2008, neither of which it was required to do. Why would the Defendants willingly and without provocation disclose their alleged fraud? If they knew that the additional patient data would finally expose their scheme, why wouldn't they just keep that data under wraps and move onto a Phase III trial? And why wouldn't they have sold their substantial stock positions before the conference rather than suffer the financial hit they experienced when the stock fell? The truth is, the facts support an inference that Defendants acted in good faith, which inference is far more compelling than the inference Plaintiff urges the Court to draw. For these and the other reasons set forth in the relevant briefing, Defendants respectfully ask the Court to dismiss the Complaint with prejudice.

II. THE COMPLAINT FAILS TO ADEQUATELY ALLEGE FALSITY.[1]

Plaintiff does not allege that Rigel's statements in December 2007 regarding the efficacy of R788 were false or misleading in any way. Instead, Plaintiff's Opposition – like its Complaint – focuses on two sets of allegations: (1) that the Company should have provided additional details at that time regarding the study's design, namely the country of residence of the patients, and (2) that the Company should have provided additional data regarding all adverse events experienced by the trial participants no matter how mild or clinically insignificant. For the additional reasons

[1] Plaintiff's failure to adequately allege materially false statements undermines all its claims, and, therefore, all claims should be dismissed. Plaintiff claims that its Section 11 and 12 claims are not based on fraud and therefore not subject to the requirements of Rule 9(b). However, because the Complaint repeats each and every allegation listed for its Section 10(b) claim as the basis for its Section 11 and 12 claims (¶ 159 & ¶ 167), those claims are grounded in fraud and must be pled with particularity. *Rubke v. Capital Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009) ("Where . . . a complaint employs the exact same factual allegations to allege violations of section 11 as it uses to allege fraudulent conduct under section 10(b) of the Exchange Act, we can assume that it sounds in fraud."); *see also In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1404-05 (9th Cir. 1996). Plaintiff's effort to disclaim a fraud theory is unavailing. *Stac Elecs.*, 89 F.3d at 1405 n.2 (a "nominal" disclaimer of fraud is "unconvincing where the gravamen of the complaint is plainly fraud and no effort is made to show any other basis for the claims . . .").

stated below, those claims must fail.

A. Plaintiff's Allegations Regarding Country-specific Data Are Based on Fundamental Mischaracterizations of that Data.

Although Plaintiff's Opposition argues that Rigel reported "false positive results" (Opp. at p. 3:15), the Complaint is more circumspect, alleging that, by failing to report response rates by country, Rigel "*may have* overstated the dose response." (¶ 59.) In either case, the facts alleged in the Complaint do not support those allegations.

Plaintiff argues that the country-specific response rates were "important information" because the higher response rates in Mexico "*may have* overstated the dose response." (¶ 59 (emphasis added).) Relying on rhetoric instead of required facts, Plaintiff leaps to the conclusion that Rigel "skew[ed] the data in favor of R788" and that the country interaction "put a big question mark" next to the efficacy results. (Opp. at pp. 7:7 & 8:5-6.) But Plaintiff never provides a plausible argument as to why the cumulative data disclosed in December 2007 "skewed" the data in favor of R788 as compared to the country-specific data. The December 2007 press release states that the groups "treated with R788 at 100mg and 150mg po bid (orally, twice daily) showed higher ACR20, ACR 50, ACR70 and DAS28 response rates than the placebo group" and then provides a table with additional data. (Declaration of Shannon M. Eagan in support of Defendants' Motion to Dismiss ("Eagan Decl.") Ex. B (12/13/07 Form 8-K) at 1.) For example, the table shows that 65% of patients on R788 in the 100mg group had an ACR20 response rate compared to just 38% of the patients in that group on placebo. Thus, 27% more of the patients on R788 experienced an improvement measured at the ACR20 level. In the tables contained in Plaintiff's Opposition, the country-specific data indicates that, of that same group, 28% more of the U.S.-enrolled patients on R788 experienced an improvement at the ACR20 level compared to those on placebo (52% on R788 compared to 24% on placebo), while 20% more of the Mexican-enrolled patients experienced similar results (75% on R788 compared to 55% on placebo). It strains credulity to argue that this additional data presents "a state of affairs that

differ[ed] in a material way" (Opp. at p. 7:10) from the cumulative data.[2] If Plaintiff's Complaint were to succeed (a complaint rooted in a fundamental aversion to all averages), no summary data regarding clinical trials would ever be safe from attack, and a new rule requiring the disclosure of all raw data would result.

Plaintiff also argues that the cumulative results were misleading because patients in Mexico had higher response rates in both the placebo and treated arms than did the U.S. patients and, thus, the data may have overstated the dose response. But they never even attempt to explain why. Rigel never trumpeted that a particular percentage of patients receiving R788 had particular ACR scores. Rather, as reflected in the second sentence of the December 2007 press release, the Company focused on the fact that patients in the trial receiving certain dosages of R788 showed higher response rates than those on placebo.

Further, the only one who seems conveniently confused by this distinction is the Plaintiff. Plaintiff selectively quotes Dr. Grossbard in an effort to support its argument that the country-specific response rate was material and that Dr. Grossbard believed as much. To the contrary, Dr. Grossbard actually explained that what "mattered" was the delta in response rates between the placebo and active arms:

> The reality is the important factor is the difference between active and the control group. This has not been an issue with the approval or [sic] Orencia, has not been an issue with Actemra.… So this is just what happens sometimes in clinical research and, I think, is of no consequence in terms of the efficacy of the drug.

(Eagan Decl. Ex. G (10/27/08 trans.) at p. 2.) Even the analyst reports cited by Plaintiff uniformly rejected the notion that the country specific response rates were important information. (*See, e.g., id.* Ex. H (10/27/08 Credit Suisse, cited at ¶¶ 60, 66, 129) at p. 2 ("While it is true that one can see the 'absolute' ACR 20 score is lower in the US than Mexico, the *important measure* is the benefit over placebo."); Ex. J (10/28/08 Oppenheimer, cited at ¶¶ 69, 70, 72, 96, 129) at p. 2 ("[T]he efficacy of R788 remains clear and was *not materially skewed* by geographic

[2] Each of Plaintiff's criticisms regarding the Company's failure to disclose country-specific data, including the fact that more Mexican patients were enrolled in the 150mg group than U.S. patients, suffer from the same defects.

distribution."); Ex. I (10/28/08 Jefferies, cited at ¶ 129) at p. 1 ("*Of key importance* though, the difference between the response rates in the R788 and placebo groups were the same across the two locations – about 20-25%. . . . [W]e note such differences are common in RA trials and have been observed with both Orencia (FDA approved) and Actemra (approval pending).") (emphasis added).)

B. Rigel's Decision to Discuss Only Moderate and Severe Adverse Effects Was Not Materially Misleading.

Plaintiff continues to rely on mischaracterizations of the initial top-line disclosures in December 2007 to support its argument that the later, more detailed disclosures revealed material omissions in the earlier statements. Rigel never represented that it was disclosing *all* side effects; to the contrary, both the language of its initial press release (referring to "key safety results") and the chart contained in that release make it clear that Rigel was only discussing *moderate-to-severe* adverse events. No reasonable investor could have reviewed the press release or listened to the publicly-accessible conference call and concluded the Company had discussed *every side effect observed regardless of severity*. (Eagan Decl. Ex. B. (12/13/07 Form 8-K) at 2; Ex. C (12/13/07 trans.) at 3.) Further, unlike the cases cited by Plaintiff, there are no allegations that Defendants failed to disclose key safety data. *See In re Connectics Corp. Sec. Litig.*, 2008 U.S. Dist. LEXIS 62515, *21-*22 (N.D. Cal. Aug. 14, 2008) (cited in Opp. at p. 16); *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 28 (D. Mass. 2004) (allegations that the FDA had a "zero tolerance" policy for undisclosed side effect) (cited in Opp. at p. 16). In reality, Plaintiff fails to allege a single fact to support the claim that the omission of mild cases of side effects threatened the commercial viability of R788. The alleged omissions are therefore immaterial. *Masters v. GlaxoSmithKline*, 271 Fed. Appx. 26, *50 (2d Cir. Mar. 26, 2008) (unpublished decision) ("[R]eports of harmful drug effects are immaterial—and thus need not be disclosed—unless those reports (1) show statistically significant evidence of an adverse effect; (2) establish that the adverse effect directly threatens the 'commercial viability' of the drug; and (3) show the effect poses a significant risk to the company's future earnings.").

Hypertension: The core hypertension allegation in the Complaint is that Defendants failed to disclose "there was a dose-dependent increase in average blood pressure of 20-30 mmHg in five patients (not two, as reported on December 13, 2007)." (¶¶ 6, 115, 122, 125, 136.) Apparently realizing that there is no support in the record that the trial produced any such result, Plaintiff has now abandoned that allegation. (Opp. at 12 n.5.)

Plaintiff's reconstituted claims challenge the 2007 disclosures based on the allegations that "(1) five patients (not two, as reported on December 13, 2007) experienced hypertension; (2) the increase in blood pressure was dose dependent; and (3) the magnitude of the increase in blood pressure was as high as 30 mmHg." (Opp. at 12 n.5.) As with each of the Patient Data Claims discussed below, these claims amount to little more than the argument that, though the Company disclosed the most significant safety results (that is, side effects), it should have also disclosed related, but less significant results as well.[3] In December 2007, Rigel disclosed that two patients in the trial had experienced hypertension during the trial of a moderate or greater severity. (Eagan Decl. Ex. B. (12/13/07 Form 8-K) at 2.) Plaintiff does not allege that that statement was false, or that more than two patients experienced hypertension of moderate or greater severity. The undisputed truth is that there were only two. Instead, Plaintiff argues that the statement was misleading because three other patients experienced hypertension of a severity less than moderate, one patient had an increase in blood pressure as high as 30 mmHg, and there was a small dose-dependent increase in average blood pressure. Plaintiff fails to provide a plausible rationale for why this additional information would have been material in light of the disclosures that were made.

As for the lack of disclosure regarding the cases of mild hypertension, Plaintiff fails to demonstrate how the omission of incidents of *mild* hypertension is a concealment of risks that would materially affect the market's perception of R788's potential value. A reasonable investor confronted with the December 2007 press release containing data regarding cases of moderate or

[3] It is worth noting that the Phase IIa trial at issue was designed to test R788's efficacy, and that, as Dr. Grossbard stated on December 13, 2007, the drug's safety profile was "going to be a close focus of the future program." (Eagan Decl. Ex. C (12/13/07 trans.) at 3.)

more severe hypertension would conclude that the summary data did not include less pronounced hypertension. Dr. Grossbard's statements during the conference call confirmed that understanding:

> The incidence of reported *moderate* hypertension was quite low, although the way the case report forms are filled out an occasional patients [sic] had a notation for his systolic blood pressure increase, and an occasional one had diastolic pressure increase. And it is hard to know exactly what that means, so I'm reporting to you here those where the case report forms noted, hypertension of *moderate* severity.

(Eagan Decl. Ex. C (12/13/07 trans.) at 3 (emphasis added).) In fact, the market appreciated such a possibility in December 2007. (*See, e.g., id.* Ex. D (12/13/07 CIBC World Markets, cited at ¶¶ 50, 79, 82, 83) at p. 4 ("Rigel did not report the rates of mild hypertension in this study. However, even if mild hypertension were to be observed, we believe this would likely be acceptable in the moderate-to-severe RA setting….").)

As for the fact that the largest increase in blood pressure observed was as high as 30 mm Hg, Plaintiff fails to explain why this additional detail would be material. Rigel disclosed in December 2007 that two patients experienced moderate to severe hypertension. If the patient who saw an increase in his or her blood pressure of 30 mm Hg was one of those two patients, then it is unclear why detail about the increase would add anything meaningful to the initial disclosures. If the patient was not one of the two experiencing moderate or severe hypertension, then it is unclear why a potentially transitory increase in blood pressure that did not result in hypertension would be material to investors. Further, as Dr. Grossbard made clear, a single reading of a 20-30 mm Hg increase in blood pressure has little clinical meaning.[4] (*Id.* Ex. G (10/27/08 trans.) at p. 4.) Because of this, physician guidelines issued by the United States

[4] Plaintiff's claim that Dr. Grossbard "acknowledged" that the increase in hypertension was "of crushing importance to everybody" is demonstrably false. (¶ 62.) Plaintiff claims that Dr. Grossbard was responding to a question about whether the average increase in the 150 mg cohort included patients whose dose of R788 was reduced, but an accurate reading of the October 27, 2008 transcript shows that Dr. Grossbard was responding to an entirely different question. Instead, Dr. Grossbard was asked whether patients who had their doses reduced did so *either three weeks or five weeks* into the study period. (Eagan Decl. Ex. G (10/27/08 trans.) at p. 8-9.) Thus, Dr. Grossbard's statements about "crushing importance" are not related to the number of patients or R788's effect on blood pressure at all.

government recommend that a doctor wait one or two months to monitor blood pressure readings before determining whether to use anti-hypertensive drugs to treat Stage 1 or Stage 2 hypertension. (*See* Supplemental Eagan Decl., Ex. V (U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality "Hypertension Guidelines" (last verified Nov. 28, 2006) at p. 7.) This is because an individual's blood pressure can vary greatly and physicians do not place much value on a single reading.[5]

Finally, Plaintiff argues that Rigel should have disclosed in December 2007 that there was a dose-dependent average increase in blood pressure. The argument fails on several fronts. First, there is not a single allegation in the Complaint that Defendants had access in December 2007 to the data that would allow them to make such a determination or any allegation that they were aware of such an effect at that time. Dose-dependency is not a side effect, but rather describes when the effect of a drug changes as the dose of the drug changes.[6] Second, Plaintiff completely fails to allege that such small increases in average blood pressure are clinically significant in any way. Third, the Company disclosed that there were a small number of patients that experienced moderate to severe hypertension, a medical condition that often requires treatment. In light of that fact, it is unclear what information regarding average blood pressure levels would add. And finally, at least one analyst understood, based on the information previously disclosed by the Company in 2007, that a dose-dependent increase in blood pressure should not have been a surprise in 2008. (*See, e.g., id.* at Ex. H (10/27/08 Credit Suisse, cited at ¶¶ 60, 66, 129) at p. 1 ("In terms of toxicity, R788 had a dose-dependent increase in blood pressure (BP), which should not have been a surprise as the company has talked about the effect on BP since the data were

[5] Analysts agreed with Dr. Grossbard's assessment that an isolated increase in blood pressure has no meaning. (*Compare* Eagan Decl. Ex. G (10/27/08 trans.) at p. 4 and Ex. N (11/3/08 trans.) at p. 10 *with* Ex. I (10/28/08 Jefferies, cited at ¶ 129) at p. 1 ("Our physician consultants do not see these BP increases as clinically meaningful or an important impediment to R788 approval – and we concur.").)

[6] Even if Defendants had access in 2007 to data indicating the number of patients that had experienced hypertension of any severity, such data would not have suggested a dose-dependent effect given that mild-to-severe levels of hypertension were observed in three patients in the 100 mg dose category, but only in two patients in the 150 mg treatment arm. (Eagan Decl. Ex. M (Nov. 2008 Article cited at ¶¶ 58, 68, 71, 73, 74) at p. 3315.)

first presented.") and Defs.' Mem. at p. 20 n.15.)[7]

Other safety results: Plaintiff's Opposition also argues that Rigel's disclosures in 2007 were misleading because they did not include additional detail regarding patients in the trial who experienced mild increases in liver enzyme levels, neutropenia, diarrhea and upper gastrointestinal (GI) side effects. As set out in Defendants' Opening Brief (Defs.' Mem. at pp. 15-19), Plaintiff does not allege that the information disclosed in 2007 regarding more severe side effects was inaccurate in any way. Nor does it dispute that a reasonable investor reviewing the 2007 disclosures would have understood that only the more severe occurrences of these side effects were disclosed. Rather, once again, Plaintiff simply argues that more detail is required, without providing any explanation as to why such detail would be material.

Plaintiff's core argument here appears to be based on misquoted analyst reports. The truth is, none of those reports support the notion that any of this information was considered material by anyone. For example, an Oppenheimer analyst cited by Plaintiff regarding liver enzyme levels stated in December 2007 that the data "suggested a possible association with LFT elevations" and later wrote that the October 2008 data "*confirms*" the association. (Opp. at pp. 14:27-15:3 (emphasis added).) (*See* Eagan Decl. Ex. H (10/27/08 Credit Suisse, cited at ¶¶ 60, 66, 129) at p. 3 ("[T]his level of LFT abnormality is likely no different [than] what could be expected with methotrexate alone . . .").) That analyst went on to conclude that R788's side effect profile was "acceptable thus far." (¶ 69.) With regard to diarrhea and upper GI effects, Plaintiff cites the fact that two analysts included the number of cases of diarrhea and upper gastrointestinal side effects in summary tables in their reports in 2008. (Opp. at pp. 15:21-16:7.) That fact hardly renders Rigel's previous statements materially false. In fact, the RBC report listed many other mild side

[7] Other analyst reports confirm that investors understood R788's effect on blood pressure and were not misled in any way. Plaintiff selectively quotes Credit Suisse analyst Aberman's report, that such a raise in blood pressure "could precipitate significant morbidity acutely" (Opp. at p. 12:2 & 12:15), but ignores the remainder of Aberman's report, which repeatedly states that there was nothing surprising about the October 2008 disclosures and that "new data [did] not dramatically change our view." (*Compare* Opp. at pp. 11:25-12:5 *with* Eagan Decl. Ex. H (10/27/08 Credit Suisse, cited at ¶¶ 60, 66, 129) at p. 1) ("[T]he company has talked about the effect on [blood pressure] since the data were first presented.").)

effects like headache, dizziness, rash and fatigue; yet, none of that data is inconsistent with earlier disclosures. (*See* Eagan Decl. Ex. L (10/28/08 RBC, cited at ¶¶ 59, 64, 65, 87, 96, 128) at p. 3.)[8]

C. Rigel's Forward-Looking Statements About Partnering Prospects Are Not Actionable.

Plaintiff claims Rigel's statement about "putting the partnership in place as early as the early part of next year" concerned a current business condition and was not subject to the PSLRA's safe harbor. (Opp. at p. 24:10-16.) It is wrong. As Judge Walker has explained, the definition of forward-looking statements includes: "statements containing projections of revenues, income, earnings per share, management's plans or objectives for future operations and predictions of future economic performance." *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 880 (N.D. Cal. 2004) (*citing* 15 USC § 78u-5(i)(1)(A)-(C)). A present-tense statement may be forward-looking "'if the truth or falsity of the statement cannot be discerned until some point in time after the statement is made.'" *Id.* (*quoting In re Splash Tech. Holdings, Inc. Sec. Litig.*, 2000 U.S. Dist. LEXIS 15369, *17 (N.D. Cal. Sept. 29, 2000) and *citing Harris v. Ivax Corp.*, 182 F.3d 799, 805 (11th Cir. 1999)). Clearly, a statement regarding when and whether Rigel

[8] In a Statement of Recent Decision filed on November 3, 2009, Plaintiff argues that *Siracusano v. Matrixx Initiatives, Inc.*, --- F.3d ---, 2009 WL 3448282, at *10-*11 (9th Cir. Oct. 28, 2009) supports its argument that Defendants knowingly made material false statements about R788's efficacy and safety results. Although the Ninth Circuit in that case did reject the reasoning of some of the cases cited in Defendants' opening brief as applied to those facts, the decision has no broader applicability to this case and does not provide support for Plaintiff's arguments. In *Siracusano*, a manufacturer of a nasally-applied cold remedy, allegedly failed to disclose, among other things, that a number of patients had complained that its product caused anosmia, a temporary or permanent loss of smell; that nine suits had been filed against the company; and that the FDA was investigating the product. Reversing the dismissal of the action, the Ninth Circuit, viewing the totality of the evidence, determined that the potential problems with the product, as reflected in repeated warnings and complaints and multiple lawsuits, were significant enough that a reasonable investor would want to know about them. *Id.* at *10-*11. The extreme pattern of conduct alleged in *Siracusano* bears no resemblance to that alleged here. Whereas in *Siracusano* the defendants were alleged to have utterly concealed repeated reports about potential serious side effects and even disparaged and threatened persons who made such reports public, here the most that can be said about Rigel is that it disclosed the *most significant* side effects of R788 (those considered "moderate" to "severe") while not including in its initial reports the *least significant* ("mild") side effects.

would enter into a partnership was a projection that could only be verified in the future and is subject to the PSLRA's safe harbor provisions.[9]

D. Plaintiff's Reliance on the Movement in Rigel's Stock Price Is Not Sufficient to Establish Materiality.

Unable to explain why investors would consider additional detail regarding mild side effects material, Plaintiff repeatedly relies on the increase in Rigel's stock price in December 2007 and the drop in the price in October 2008 to support its claim that the additional patient data disclosed in 2008 was material. That reliance is misplaced. *See, e.g., In re Seagate Tech. II Sec. Litig.*, 843 F. Supp. 1341, 1372 (N.D. Cal. 1994) (decline in stock price "is not sufficient by itself to establish materiality, because the change in price may be caused by new information" unrelated to the alleged fraud) (internal quotations omitted); *In re Hansen Natural Corp. Sec. Litig.*, 527 F. Supp. 2d 1142, 1161 (C.D. Cal. 2007). As set out in Defendants' opening brief (Defs.' Mem. at pp. 7:25-8:6), Plaintiff ignores the most likely explanation for the drop in Rigel's stock price in 2008. At the ACR meeting in October 2008, unfounded rumors circulated that R788 prolonged the "QT/QTc interval" of the heart, which can be associated with fatal cardiac arrhythmias. (Eagan Decl., Ex. G (10/27/08 trans.) at pp. 20, 23.)[10] Analysts later suggested that rumors about QTc prolongation pushed Rigel's stock lower. (*See, e.g., id.* at Ex. J (10/28/08 Oppenheimer, cited at ¶¶ 69, 70, 72, 96, 129) at pp. 1, 4.)

III. PLAINTIFF HAS NOT ALLEGED SPECIFIC FACTS GIVING RISE TO A STRONG INFERENCE OF SCIENTER.

Plaintiff also fails to meet its burden to plead scienter. It is well settled that a complaint will survive a motion to dismiss only "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the

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[9] Further, even if the statement that Rigel was "on track for putting a partnership in place in the early part of 2009" were considered a statement regarding a current business condition, Plaintiff has failed to allege facts showing that this was false when made in October 2008 or that Defendants knew it was false.

[10] On February 3, 2009, Rigel reported that "there were no significant effects on the QT/QTc intervals of participants in either the 100 mg bid or the 300 mg bid R788 dosage groups." (Eagan Decl. Ex. R (2/3/09 8-K/PR) at p. 2 of Exhibit 99.1 to the Form 8-K.)

facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Further, to establish a strong inference of scienter in the context of an omissions case, "the plaintiff must plead 'a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). Plaintiff has failed to satisfy these requirements. In its brief, Plaintiff does not even attempt to undertake the comparison required by *Tellabs* between the inference it urges on the Court and the other inferences a reasonable person would draw from the allegations and facts subject to judicial notice. That failure is telling and, alone, provides sufficient grounds to grant the motion to dismiss.

Plaintiff does argue, however, that it has adequately plead scienter based on the allegations that the individual Defendants had a motive to engage in fraudulent activity due to Rigel's need to raise capital, that they knew that the additional patient data would make it more difficult to raise that capital, and that the five officer Defendants would benefit through larger bonuses, larger salary increases and increased option values if they reported positive results.[11] Although the Complaint does not include any information regarding previous bonuses or salary increases from which comparisons might be drawn, the Complaint does allege that the five officer Defendants received an average bonus of $391,800 in 2007 and an average salary increase in 2008 of $62,640. (¶¶ 104-105.) Plaintiff argues that scienter should be inferred from these facts.

Plaintiff ignores several other facts that are relevant to determining what inference is the most cogent and compelling: (1) Although Rigel did not disclose all the details Plaintiff claims it should have in 2007, the Company did disclose the most serious side effects that patients in the study experienced. (2) The Company voluntarily disclosed the additional detail – the detail that

[11] Plaintiff cites *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069 (N.D. Cal. 2005) and *Zucco* in support of its argument that Rigel's compensation structure served as a motive for the alleged fraud. Interestingly, the courts in both cases dismissed the actions due to, among other things, a failure to adequately allege scienter despite the link between the companies' compensation structure and the alleged frauds.

Plaintiff alleges it tried so hard to conceal in 2007 – at a medical conference and in a medical journal in the fall of 2008. (*See* Eagan Decl. Ex. G (10/27/08 trans.); Ex. M (November 2008 Article) at p. 3315.) There is no allegation that the Company was under any sort of compulsion to do so. (3) During the period in which the price of Rigel's stock was allegedly inflated due to the fraudulent conduct of Defendants, none of the Defendants sold any of their stock in the Company. (*See id.* ¶ 21-22, Ex. T and Ex. U (Form 4s).) (4) During that same period, each of the five officer Defendants actually increased the number of exercisable options and two Defendants actually increased the number of shares that they owned. (*See id.* ¶ 23.) And (5) by holding on to their stock in the weeks leading up to the 2008 ACR conference when they allegedly knew that "the truth would come out," those five Defendants together lost in excess of $18.7 million.[12]

Defendants submit that the far more compelling inference to be drawn from these facts and allegations is that they acted in good faith, without the intent or purpose to defraud anyone. That is the only inference that can be reconciled with all those facts, including, most importantly, the undisputed fact that the Company voluntarily disclosed the additional patient data to a scientific audience. Such disclosure is consistent with a pure, non-corrupt motive, not a motive to deceive. Had Defendants actually been acting with scienter, one would expect that they would have continued to conceal the allegedly material information and proceed to a Phase III trial. They certainly would not have disclosed their own fraud. Further, while Plaintiff alleges that bonuses and salary increases may have created a motivation to engage in a fraud, the facts show that the Defendants suffered a far larger financial loss by holding onto their existing shares and increasing their financial exposure to the Company. Had the Defendants believed that the 2008 disclosures would somehow reveal a fraud, they certainly would have sold at least some of their stock and options before the conference. When these allegations are considered in total, the inference of scienter is far less compelling than the inference of good faith; in fact, it is far from cogent.

[12] According to the Complaint, the price of Rigel stock fell $5.57 on October 28, 2008, and $.67 on February 3, 2009, as a result of the alleged fraud being disclosed. (¶¶ 15, 17.) According to SEC filings, the five officer Defendants owned roughly 3 million shares outright or through options during that time period. (*See* Eagan Decl. ¶ 23.)

Further, Plaintiff has failed to make any allegations that suggest that Defendants' conduct was an extreme departure from standards of ordinary care or that they consciously or recklessly decided to conceal the additional patient data in an effort to mislead investors. Plaintiff's Complaint fails to allege the existence of a single document, a single internal report or a single confidential witness supporting the idea that any Defendant believed a difference in response rates among patients in different countries, mild side effects, a minor dose-dependent effect on blood pressure, or a single reading of elevated blood pressure should have been disclosed. *See, e.g., In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) (finding general allegations of negative internal reports and an alleged "conspiracy of silence" among defendants insufficient to allege strong inference of scienter). Without such allegations, Plaintiff cannot meet its burden.

Finally, the cases Plaintiff cites to support its contention that routine business objectives are sufficient to allege scienter, *Howard v. Everex Sys., Inc.*, 228 F.3d 1057 (9th Cir. 2000) and *In re U.S. Aggregates, Inc. Sec. Litig.*, 2003 WL 252138 (N.D. Cal. Jan. 24, 2003), provide no such support. In *Howard*, the Ninth Circuit concluded that a demonstration of a CEO's possible motive, combined with red flags regarding the company's financial condition and a signed financial statement by the CEO in the face of the company's alarming financial condition, was evidence sufficient for a jury to find scienter. 228 F.3d at 1064. Notably, the Ninth Circuit emphasized that a mere showing of motive and opportunity is not enough to survive a motion to dismiss. *Id.* In *U.S. Aggregates*, the complaint contained particularized allegations from confidential witnesses that defendant CFO was not only aware of accounting improprieties at the company, but directed them. 2003 WL 252138, at *4. Plaintiff's Complaint is devoid of any similar allegations or detail. As the Ninth Circuit explained in *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027 (9th Cir. 2002), "If scienter could be pleaded by alleging that officers and directors possess motive and opportunity to enhance a company's business prospects, 'virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions.'" 284 F.3d at 1038 (*quoting Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995)). In that case, the Court held that allegations that defendants were

motivated to impress lenders to secure funding, that defendants received reports indicating flat sales but made public statements to the contrary, and that the CEO sold company stock during the purported class period were insufficient to allege fraud. *Id.* at 1035-38; *see also Ree v. Pinckert*, No. C99-0562 MMC, slip op. at 17 (N.D. Cal. Mar. 28, 2000) (rejecting secondary stock offering as basis to establish scienter) (attached as Ex. W to Supplemental Eagan Decl.).

IV. CONCLUSION

Defendants respectfully request that the Court grant Defendants' motion to dismiss Plaintiff's Complaint with prejudice. *In re FVC.com, Inc. Sec. Litig.*, 136 F. Supp. 2d 1031, 1040-41 (N.D. Cal. 2000), *aff'd*, 32 Fed. Appx. 338, 339-340 (9th Cir. 2002) (even an initial complaint may be dismissed without leave to amend, where it is clear that amendment would be futile).

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